

fiber optic filaments;

- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient;
- (v) a port defined by surfaces of one of the lumens of said multi-lumen main body portion, said port for injecting a fluid into a blood stream of a patient; and
- (vi) a fiber optic apparatus [associated with the catheter] including [optical] said fiber optic filaments, said fiber optic filaments disposed in said at least one lumen for holding and supporting said fiber optic filaments, and said fiber optic filaments extending from inside [the working length of] said multi-lumen main body portion [and into] to a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends [the working length of] from the temperature measurement apparatus along said multi-lumen main

body portion [and into] to a housing associated with said multi-lumen main body portion;

(g) an external thermal element is [placed] mounted on said multi-lumen main body portion near the distal end of said multi-lumen main body portion;

(h) connectors extend from said external thermal element along [the working length of] said multi-lumen main body portion [to be connected] for connection to a thermal element housing at the proximal end of said multi-lumen main body portion;

(i) said external thermal element and said temperature measurement apparatus are [is] operative with an external apparatus [to provide] for providing a measurement of continuous cardiac output of a patient; and

(j) said fiber optic apparatus is cooperative with said external apparatus for providing a measurement of mixed venous oxygen saturation of blood of the patient.

46. (Amended) [The multi-lumen, multi-purpose cardiac catheter of claim 45]

A multi-lumen, multi-purpose cardiac catheter comprising:

(a) a multi-lumen main body portion;

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

(c) an interface connecting said multi-lumen main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient;
- (v) a fiber optic apparatus including said fiber optic filaments, said fiber optic filaments in said at least one lumen for holding and supporting said fiber optic filaments, and said fiber optic filaments extending from inside said multi-lumen main body portion to a fiber optic coupler associated with the catheter; and
- (vi) a necked-down portion near the distal end of said multi-lumen main body portion;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends from the temperature measurement apparatus along said multi-lumen main body portion to a housing associated with said multi-lumen main body portion;

(g) an external thermal element is mounted on said

multi-lumen main body portion near the distal end of said multi-lumen main body portion;

(h) connectors extend from said external thermal element along said multi-lumen main body portion for connection to a thermal element housing at the proximal end of said multi-lumen main body portion;

(i) said external thermal element and said temperature measurement apparatus are operative with an external apparatus for providing a measurement of continuous cardiac output of a patient;

(j) said fiber optic apparatus is cooperative with said external apparatus for providing a measurement of mixed venous oxygen saturation of blood of the patient; and

[wherein:

C) (a) said multi-lumen main body portion includes a necked-down portion;

(b) said necked-down portion is near the distal end of said multi-lumen main body portion; and

(c)]

(k) said external thermal element is [disposed in] mounted on said necked-down portion.

47. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 46, wherein[:

(a) said necked-down portion is 5-10 centimeters in length and

(b)] said necked-down portion is [disposed] approximately 14-15 centimeters from the distal end of said multi-lumen main body portion.

ne 48. (Not Amended) The multi-lumen, multi-purpose cardiac catheter of claim 46 wherein said external thermal element comprises a heater coil wound about said necked-down portion.

49. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said temperature measurement apparatus comprises a thermistor which is [adjacent the distal end of] distal said heater coil.

C2 50. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said heater coil comprises windings pitched at a center-to-center spacing sufficient to separate adjacent coils from one another.

ne 51. (Not Amended) The multi-lumen, multi-purpose cardiac catheter of claim 48, wherein said heater coil is surrounded by a thin outer sheath to prevent said external thermal element from directly contacting the patient's blood.

52. (Amended) ~~The multi-lumen, multi-purpose cardiac catheter of claim 51, wherein [said heater coil and] an outer sheath diameter of said thin outer sheath [generally approximate the] approximates an outer main body portion diameter of said multi-lumen main body portion, thereby facilitating a smooth insertion of said multi-lumen main body portion into the body of the patient.~~

C3 53. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein:

(a) said port is distal said interface [at least one lumen of said multi-lumen main body portion is an injectate lumen] and

(b) said [injectate] lumen having the surfaces defining said port is an injectate lumen and said injectate lumen and said port enable [is dedicated to proximal fluid infusion, thereby enabling] injection of an injectate fluid into the blood stream of the patient [to obtain thermal dilution readings at said thermistor to provide values for use in calculating intermittent cardiac output values].

54. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein said external thermal element comprises a thin film member spirally wound about said multi-lumen main body portion [near] at approximately fourteen centimeters from the distal end of said multi-lumen main body portion.

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C3 55. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein:

(a) said external thermal element comprises a heating filament printed on two opposing sides of a substrate [as a sandwich] and

(b) said substrate is a thin material that is capable of being incorporated into a filament material that is flexible and has the ability to bond with an adhesive.

56. (Amended) The multi-lumen, multi-purpose cardiac catheter of claim 45, wherein said external thermal element comprises a layer of material with high thermal conductivity [to help create a more] for providing [uniform surface] temperature uniformity on a surface of said external thermal element.

Sub H
57. (Amended) A multi-lumen, multi-purpose cardiac

catheter comprising:

- (a) a multi-lumen main body portion;
- (b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and
- (c) [a manifold] an interface connecting [providing an interface between] said multi-lumen main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient;
- (v) a port defined by surfaces of one of the lumens of said multi-lumen main body portion, said port for injecting a fluid into a blood stream of a patient; and
- (vi) a fiber optic apparatus [associated with the catheter] including [optical] said fiber optic filaments, said fiber optic filaments

disposed in said at least one lumen for holding and supporting said fiber optic filaments, and said fiber optic filaments extending from inside [the working length of] said multi-lumen main body portion [and into] to a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends [the working length of] from the temperature measurement apparatus along said multi-lumen main body portion [and into] to a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is [disposed] near the distal end of said multi-lumen main body portion;

(h) an external thermal element is [placed] mounted on said necked-down portion;

(i) connectors extend from said external thermal element along [the working length of] said multi-lumen main body portion [to be connected] for connection to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) said external thermal element and said temperature measurement apparatus are [is] operative with an external apparatus [to provide] for providing a measurement of continuous cardiac output of a patient; and

(k) said fiber optic apparatus is cooperative with said

external apparatus for providing a measurement of mixed venous oxygen saturation of blood of the patient.

58. (Amended) A multi-lumen, multi-purpose cardiac catheter comprising:

- (a) a multi-lumen main body portion;
- (b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

(c) [a manifold] an interface connecting [providing an interface between] said main body portion and said plurality of extension tubes,

wherein:

- (d) said multi-lumen main body portion comprises:
 - (i) at least one lumen for holding and supporting fiber optic filaments;
 - (ii) at least one lumen for receiving thermal element connectors;
 - (iii) at least one lumen for receiving a device for temperature measurement;
 - (iv) at least one lumen associated with a balloon mounted at the distal end of said multi-lumen main body portion for assisting in placement of said multi-lumen main body portion in a patient; and
 - (v) a fiber optic apparatus [associated with the catheter] including [optical] said fiber optic filaments, said fiber optic filaments [disposed] in said at least one lumen for

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holding and supporting said fiber optic filaments, and said fiber optic filaments extending from inside [the working length of] said multi-lumen main body portion [and into] to a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends [the working length of] from the temperature measurement apparatus along said multi-lumen main body portion [and into] to a housing associated with said multi-lumen main body portion;

(g) a necked-down portion of said multi-lumen main body portion is [disposed] near the distal end of said multi-lumen main body portion;

C3 (h) an external thermal element is [placed] mounted on said necked-down portion;

(i) connectors extend from said external thermal element along [the working length of] said multi-lumen main body portion [to be connected] for connection to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) at least one lumen of said multi-lumen main body portion comprises an injectate lumen;

(k) said injectate lumen is dedicated to proximal fluid infusion;

(l) said external thermal element and said temperature measurement apparatus are [is] operative with an external

apparatus [to provide] for providing a measurement of continuous cardiac output of a patient;

(m) said fiber optic apparatus is cooperative with said external apparatus for providing a measurement of mixed venous oxygen saturation of blood of the patient; and

C3 (n) said injectate lumen has surfaces defining a port and said injectate lumen and said port enable [enables] injection of an injectate fluid into the blood stream of the patient [to obtain thermal dilution readings at said temperature measurement apparatus to provide values for use in calculating intermittent cardiac output values].--

[Please add the following new claims.]

Sub D5 --59. The multi-lumen, multi-purpose cardiac catheter of claim 46, wherein said multi-lumen main body portion further comprises at least one injectate lumen for injecting a fluid into the blood stream of the patient, said injectate lumen having surfaces defining a port.

60. The multi-lumen, multi-purpose cardiac catheter of claim 59, wherein

C4 (a) said port is distal said interface and

(b) said injectate lumen and said port enable injection of an injectate fluid into the blood stream of the patient.

Sub D6 61. A multi-lumen, multi-purpose cardiac catheter comprising:

(a) a multi-lumen main body portion;

(b) a plurality of extension tubes, each one of said plurality of extension tubes being connected to a respective lumen of said multi-lumen main body portion; and

(c) an interface connecting said multi-lumen main body portion and said plurality of extension tubes,

wherein:

(d) said multi-lumen main body portion comprises:

- (i) at least one lumen for holding and supporting fiber optic filaments;
- (ii) at least one lumen for receiving thermal element connectors and associated with a balloon mounted at the distal end of said multi-lumen main body portion;
- (iii) at least one lumen for receiving a device for temperature measurement;
- (iv) at least one lumen dedicated to measuring distal catheter pressure;
- (v) a fiber optic apparatus including said fiber optic filaments, said fiber optic filaments disposed in said at least one lumen for holding and supporting said fiber optic filaments, and said fiber optic filaments extending from inside said multi-lumen main body portion to a fiber optic coupler associated with the catheter;

(e) a temperature measurement apparatus is mounted at the distal end of said multi-lumen main body portion;

(f) wiring extends from the temperature measurement apparatus along said multi-lumen main body portion to a housing associated with said multi-lumen main body portion;

(g) an external thermal element is mounted on said

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multi-lumen main body portion near the distal end of said multi-lumen main body portion;

(h) connectors extend from said external thermal element along said multi-lumen main body portion for connection to a thermal element housing at the proximal end of said multi-lumen main body portion;

(i) said external thermal element and said temperature measurement apparatus are operative with an external apparatus for providing a measurement of continuous cardiac output of a patient; and

C4 (j) said fiber optic apparatus is cooperative with said external apparatus for providing a measurement of mixed venous oxygen saturation of blood of the patient.

62. The multi-lumen, multi-purpose cardiac catheter of claim 61, wherein said at least one lumen dedicated to measuring distal catheter pressure comprises surfaces defining a port.

63. The multi-lumen, multi-purpose cardiac catheter of claim 62, wherein said port is for measuring distal catheter pressure.--

REMARKS

Examiner Nasser is thanked of the courtesy extended to applicants' representative during the April 16, 1996 interview. The outstanding rejections and the issues relating to the request for an interference were discussed during the interview. The examiner indicated that the versions of claims 46-52 discussed at the interview were free of the art. The

examiner also indicated that further consideration would be required to determine whether claims to be presented in this application reciting a port define the same patentable invention as any claim in the Gallup et al. patent.

Claims 45-63 are now present, claims 59-63 having been added by this amendment.

The office action objected to the specification under 35 USC 135 and rejected claims 45-58 under the first paragraph of 35 USC 112 reasoning:

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the claimed invention. Throughout the claims, applicant has referred to the working length of the multi-lumen main body portion. However, such term has not been defined in the specification. Therefore, it is unclear what applicant is referring to. For the purposes of any art rejection, the examiner has interpreted the term working length to mean the entire length of the multi-lumen main body portion. Also, in claim 53, applicant discusses making fluid injectate thermodilution measurements. However, the present invention introduces heat into the bloodstream and measures the resulting temperature change to determine cardiac output. Therefore, it is unclear how the injectate lumen enables thermodilution measurements, as the present invention does not make bolus injectate measurements.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing the disclosure, as originally filed, fails to provide support for the invention, as now claimed. Specifically, in claims 45, 57, and 58, in paragraph d(v), applicant recites that the device includes a fiber optic apparatus, including filaments disposed in the lumen, extending the working length of the multi-lumen main body portion into a fiber optic coupler. This has no basis in the specification, as all applicant has disclosed is that one of the lumens may receive a module for determining mixed venous oxygen saturation including a fiber optic bundle. This does not provide support for the filaments extending the working length of the multi-lumen main body portion, or for the fiber optic

coupler that is associated with the catheter. Hence, both limitations introduce new matter. In addition, in paragraph f, applicant has recited that wiring extends the entire working length of the multi-lumen main body portion. This limitation introduces new matter, as the specification does not provide support for any wiring extending the working length of the catheter. The examiner notes that if applicant amended the claim to recite that the wiring extended from the temperature measuring apparatus, along the length of the multi-lumen main body portion to a housing ..., it would overcome this rejection. In claim 47, applicant has recited that the necked down portion is 5-10 centimeters in length. Applicant points to page 18, lines 22-24 and page 22, lines 3-7 as providing support for these limitations. It is the examiner's position that the enumerated pages merely state that the heating filament is 5-10 cm long. No teaching of the length of the necked down portion is provided in applicant's specification. Hence, claim 47 introduces new matter, as nowhere does applicant state that the heating filament and the necked down portion are the same length. Further, in claim 49, applicant has recited that the temperature measurement apparatus comprises a thermistor which is adjacent the distal end of the heater coil. The examiner notes that this limitation has no support in the specification, as the thermistor is disclosed as being 1-2 cm from the distal end, while the heater coil is disclosed as being 14-15 cm from the distal end. Hence, the thermistor and heater coil are approximately 12-13 cm apart, which are not "adjacent". Hence, this claim introduces new matter. In claim 53 and 58, applicant recites that the injectate lumen allows injectate fluid to be injected into the blood stream to enable thermodilution measurements. While there is basis for the lumen allowing for proximal fluid infusion, there is no antecedent basis in the specification for fluid injection thermodilution measurements. On pages 27-28, applicant states that the copending McKown et al application, now US Patent 5,146,414 discusses fluid injection thermodilution, nowhere does applicant state that such fluid injectate thermodilution measurements are used with the present invention. Therefore, claims 53 and 58 introduce new matter.

Claims 45-58 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.¹

¹Office action page 2 lines 14 to page 5 line 9.

The office action also rejected claims 46-53, 57, and 58 reasoning as follows:

Claims 46-53, 57, and 58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 46 and 57 are rejected as duplicates of each other. Claims 53 and 58 are rejected as being substantial duplicates. In both cases, the dependent claims from 45, 46 and 53, recite the features that distinguish claims 57 and 58 from the claim 45. Hence, the claims duplicate each other. Claims 47-52 are rejected as being dependent on a rejected base claim. Clarification is required.²

In response, the claims have been amended in response to each of the issues raised in these rejections.

First, the recitation "the working length of" has been deleted and replaced with more definite language.

Second, the recitation in claim 53 "to obtain thermal dilution readings" has been deleted.

Third, claims 45, 57, and 58 have been amended to recite fiber optical filaments extending "from inside said multi-lumen main body portion to a fiber optic coupler associated with the catheter." This recitation is supported by the specification because page 25 lines 11-15 discloses that a fiber optics module may be inserted into one of the lumens and that the proximal end of the fiber optics could be attached to appropriate electronics. Thus, the specification teaches the fiber optic filaments inside the multi-lumen main body portion and the coupler for coupling the outputs of the fiber optics to electronics.

²Office action page 5 lines 10-19.

Fourth, paragraph f of claims 45, 57, and 58 have been amended along the line suggested in the office action.³

Fifth, the recitation in claim 47 defining the length of the necked down portion has been deleted.

Sixth, the recitation in claim 49 defining the thermistor as adjacent to the distal end of the heater coil has been amended to define the thermistor located distally from the heater coil, which is supported by page 26 lines 17-24 of the specification.


The recitations in claims 53 and 58 relating to thermal dilution measurement have been deleted.

Seventh, claims 46 and 57 are no longer duplicates since they define different limitations for the location of the external thermal element.

Eighth, claims 53 and 58 are no longer substantial duplicates because claim 58 defines the necked-down portion of the multi-lumen main body portion.

The examiner's attention is directed to the updated 37 CFR 1.607 request, the updated draft form PTO-850, and the updated proposed count, all of which are submitted herewith.

Respectfully submitted,


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³Office action page 3 line 22 to page 4 line 2.

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